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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,690	08/05/2002	Neil J. Rowley	PA-9948	3740

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GE HEALTHCARE BIO-SCIENCES CORP.
PATENT DEPARTMENT
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EXAMINER

JONES, DAMERON LEVEST

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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12/12/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/069,690		ROWLEY ET AL.	
	Examiner		Art Unit	
	D. L. Jones		1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/1/07.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 10/1/07 wherein claim 6 was amended.

Note: Claims 1-9 are pending.

RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS

2. The Applicant's arguments and/or amendment filed 10/1/07 to the rejection of claims 1-9 made by the Examiner under 35 USC 103 have been fully considered and deemed non-persuasive for reasons of record in the office action mailed 6/29/07 and those set forth below.

103 Rejections

I. The rejection of claims 1-4, 8, and 9 under 35 USC 103(a) as being unpatentable over Felder (US Patent No. 5,132,409) in view of Schott Glaswerke (DE 29609958) in further view of Walther (US Patent No. 6,200,658) is MAINTAINED.

II. The rejection of claims 1, 5, 6, 8, and 9 under 35 USC 103(a) as being unpatentable over Albert (US Patent No. 5,545,396) in view of Schott Glaswerke (DE29609958) and in further view of Walther (US Patent No. 6,200,658) is MAINTAINED.

III. The rejection of claims 1, 5, and 7-9 under 35 USC 103(a) as being unpatentable over Ardenkjaer-Larsen et al (US Patent No. 6,466,814) in view of Schott-Glaswerke (DE 29609958) and in further view of Walther (US Patent No. 6,200,658) is MAINTAINED.

Applicant's assertions may be summarized as follows. (1) The Examiner points out the Jepson type claim, but Applicant is unsure why the Examiner has focused on an analysis of the novelty of a feature of present claims when the issue at stake is an obviousness issue. Applicant asserts that the fact that a diagnostic composition comprises a non-radioactive metal complex or a hyperpolarized material in the silica coated containers of Schott is both novel and inventive. In addition, Applicant asserts that the compositions of the instant invention are not merely the results of an addition to the compositions of Schott, but that they are different to the compositions taught by Schott since the diagnostic agent is different. (2) Applicant asserts that the Examiner's logic about the combining of the references is not obvious. Furthermore, Applicant asserts that Schott teaches only solving problems for diagnostic agents which are blood and blood products. Also, Applicant asserts that the Examiner's logic ignores the issues of the suitability of the combination and motivation to combine. (3) Applicant asserts that with regard to the Albert document, only Example 2 teaches silicone and since a reference is considered for what it teaches as a whole, then the issue is that since the only teaching of Albert on container coatings is in Example 2, then the teachings do not extend to other coatings. (4) Applicant once again asserts that the Examiner has used hindsight reasoning to construct the prior art rejection. In addition, Applicant asserts that while the Examiner has responded to Applicant's hindsight assertions before, the Examiner has disregarded all alternatives apart from those which lead to the instant invention.

Essentially, the same arguments presented in earlier responses are once again presented. As previously stated, Applicant's attention is directed to the Examiners' responses of each of the previous office actions. While Applicant asserts that the Examiner should point to specific arguments, it should be noted that the same arguments are being present and the Examiners' responses are being maintained. Furthermore, since each office action is a part of the official record, it is not necessary for the Examiner to write or restate each response each time word for word when the responses are already of record.

The Examiner discussed in detail Jepson type claims to illustrate that not all portions of the claim are considered novel. The portion of the claim that is 'novel' that which follows the phrase 'the improvement comprising' found between the preamble and the body of the claim. The Examiner then went on to cite various locations in the cited prior art to illustrate that what Applicant views as being novel in the claim are disclosed in the cited prior art.

Schott establishes that it is known in the art to coat a glass container with silica to avoid leaching of substances from the glass (page 1, first complete paragraph; pages 1-2, bridging paragraph; page 2, third and fourth paragraphs). As discussed in the previous office action, what is disclosed in Applicant's preamble, a composition comprising a diagnostic agent in a container having a silica inner coating is taught in Schott. Thus, while the diagnostic agent of Schott is not necessarily the same as Applicant, the teaching of a silica coated container in combination with a diagnostic agent is known in the art. Hence, Ardenkjaer-Larsen et al, Felder et al, and Albert et al

were cited to illustrate that it is known in the art to have a diagnostic agent comprising a hyperpolarized material and a non-radioactive metal complex (Ardenkjaer-Larsen et al, see entire document, especially, abstract; column 2, lines 44-47, column 3, lines 35-48; column 6, lines 34-48; columns 28-29, claim 1; see also, Albert et al, entire document, especially, abstract; and also Felder et al, see entire document, especially, abstract; column 2, lines 13-44; and column 4, lines 23-40). Thus, the combining of the teachings of Schott and Ardenkjaer-Larsen et al, Felder et al, and Albert et al disclose that it is well known in the art to have a diagnostic agent comprising a hyperpolarize material and a non-radioactive metal complex. Therefore, the teachings necessary for the instant invention are known in the art and the interchanging of diagnostic agents in a silica coated container is within the skill of a practitioner in the art.

The teachings of Schott are not limited to blood and blood products. In the first paragraph of the document, Schott discloses that their document is directed to glass containers for storing pharmaceutical/diagnostic solutions. The paragraph goes on to disclose that the different types of glass containers are currently being used to hold blood and blood samples. In the fourth paragraph, it is disclosed that 'in some medications, a part of the active ingredients may be inactivated due to ions that are released from the glass; this is especially a problem with low-dose medications'. In the fifth paragraph, Schott discloses that Schott discloses 'it is therefore the object of the invention to find a glass container for storing pharmaceutical/diagnostic solutions...with respect to these solutions, i.e., in which the quantities of ions that leach out of the glass as a result of these solutions is minimized'. Thus, based on what is set forth in Schott,

the teachings of the reference are not limited to blood/blood products, but to glass containers for storing pharmaceutical/diagnostic solutions in general.

The teachings of Albert relied on by the Examiner were not limited to the coating of Example 2. The teaching regarding the disclosing of a diagnostic agent comprising a hyperpolarized material was also of interest as they relate to the instant invention. Furthermore, it should be noted that Example 2 illustrates that it is known in the art to coat a container in which a diagnostic agent such as the one claimed by Applicant is to be placed.

Without repeating word for word the Examiner's arguments for Applicant's hindsight assertion, the Examiner once again asserts that the prior art disclose a diagnostic agent like the one being claimed by Applicant in a coated container (e.g., Albert et al) and Schott discloses in general the coating of containers useful for pharmaceutical/diagnostic agents. Thus, in those documents, for example, one would be motivated to place the known diagnostic agent (i.e., that of Albert et al) in an 'improved' container with a silica coating (e.g., that of Schott) which is a glass container that is especially for storing pharmaceutical and diagnostic solutions.

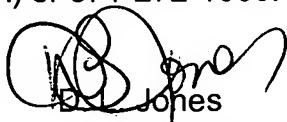
3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date

the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


D. L. Jones
Primary Examiner
Art Unit 1618

December 9, 2007